

MAR 30 2012

K113168

<b>CIBA VISION.</b> <small>Shared Passion for Healthy Vision and Better Life</small>	CIBA VISION Corporation 11460 Johns Creek Parkway Duluth, Georgia USA 30097	27-Mar-2012, v03 Page 1 of 4
<b>Delefilcon A Soft Contact Lenses</b> 510(k) Summary of Safety and Substantial Equivalence		

**510(k) Summary - K113168****1. Submitter Information:**

Company: CIBA VISION Corporation  
11460 Johns Creek Parkway  
Duluth, Georgia USA 30097

Contact Person: Alicia M. Plesnarski, RAC  
Director, Regulatory Affairs

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Date Prepared: 27-Mar-2012

**2. Device Name:**

- Common Name: Soft Contact Lens
- Trade/Proprietary Name: DAILIES TOTAL1® (delefilcon A)
- Classification Name: Daily Wear Soft Contact Lens
- Device Classification: Class II [21 CFR 886.5925 (b) (1)]

**3. Predicate Device:**

The predicate device is Johnson & Johnson VISTAKON® 1-DAY ACUVUE® TruEye (narafilecon B) soft contact lenses packaged in buffered saline. Narafilecon B lenses belong to ISO Group V (silicone hydrogel). Johnson & Johnson VISTAKON 1-DAY ACUVUE TruEye lenses have FDA 510(k) clearance per K100349, 21-May-2010.


**4. Description of Device:**

The lens material is 33% water and 67% delefilcon A, a silicone containing hydrogel with added phosphatidylcholine. The core lens material containing 33% water transitions through a water gradient to a hydrogel surface layer that exceeds 80% water. Lenses contain the color additive copper phthalocyanine, a light blue handling tint, which makes them easier to see when handling

Delefilcon A lens designs include spherical, toric, multifocal and toric multifocal lenses in the following parameter ranges:

- Diameter Range: 13.0 to 15.0 mm
- Base Curve Range: 8.0 to 9.2 mm
- Power Range: -20.00D to +20.00D
- Center Thickness: varies with design and power  
(0.09 mm for -3.00D spherical)

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Lenses have the following properties:

- Refractive index: 1.42 (hydrated)
- Light transmittance:  $\geq 93\%$  (@610 nm, -1.00D)
- Water content: 33% by weight in normal saline
- Surface water content:  $\geq 80\%$
- Oxygen permeability  $140 \times 10^{-11}$   
 $[(\text{cm}^2/\text{sec})(\text{ml O}_2/\text{ml} \cdot \text{mmHg})]$   
measured at 35°C (intrinsic Dk-Coulometric method)

Each lens is packaged in a foil-sealed plastic container containing phosphate buffered saline solution with approximately 0.3% of polymeric wetting agents consisting of copolymers of polyamidoamine and poly(acrylamide-acrylic acid) and are steam sterilized. The compatibility and package integrity of the blister pack packaging system has been demonstrated and successfully used for other marketed contact lens products, and packaged lenses are effectively steam sterilized in a validated autoclave. Blister pack containers are labeled with the lens parameters, lot number and product expiration date. The expiration date has been established through stability studies that have assessed the chemical and physical stability of the lens and integrity of the package (ability to maintain sterility). Shelf-life studies are ongoing to establish and extend the labeled expiration date.

## **5. Indications for Use:**

DAILIES TOTAL1® (delefilcon A) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters of astigmatism.


DAILIES TOTAL1® for Astigmatism (delefilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with 6.00 diopters (D) or less of astigmatism.

DAILIES TOTAL1® Multifocal (delefilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have up to approximately 1.50 diopters of astigmatism.

DAILIES TOTAL1® Multifocal Toric (delefilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in phakic or aphakic persons with non-diseased eyes. The lenses may be worn by persons who have 6.00 diopters (D) or less of astigmatism and who may require a reading addition of +3.00 diopters (D) or less.

The lenses are to be prescribed for single use, daily disposable wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

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#### **6. Description of Safety and Substantial Equivalence:**


A series of non-clinical tests were performed to characterize lens material properties and establish substantial equivalence to the predicate device. All testing was conducted in accordance with the May 1994 FDA guidance document titled *Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses* and in conformance to applicable device regulations. Results verify that delefilcon A contact lenses are non-toxic and biocompatible, have material characteristics in common with currently marketed soft contact lenses intended for vision correction and demonstrate substantial equivalence to the previously FDA cleared predicate (control) lenses listed in Table 1.

Table 1. Substantial Equivalence Comparison

	Predicate Device	New Device
Product Name	Johnson & Johnson® VISTAKON® 1-DAY ACUVUE® TruEye™ (narafilecon B)	CIBA VISION® DAILIES TOTAL1® (delefilcon A)
Intended Use	Daily Disposable Wear	Daily Disposable Wear
Mode of Action	When hydrated and placed on the cornea, lenses act as a refracting medium to focus light rays on the retina.	When hydrated and placed on the cornea, lenses act as a refracting medium to focus light rays on the retina.
510(k) Number	K100349	To be assigned
Lens Material Group**	ISO Group V	ISO Group V
Manufacturing Method	Molded	LightStream
Sterilization Method	Moist Heat	Moist Heat
Packaging	Blister Pack	Blister Pack
Handling Tint	Lt. Blue	Lt. Blue
Refractive Index	1.41	1.42
Water Content (%)	48	33
Oxygen permeability	55	140
BC/Diameter (mm)	8.5/14.2	8.5/14.1
Power (D)	various	various

\*\*Per EN ISO 18369-1/Amd.1:2009

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## Conclusions drawn from Studies

### Nonclinical Testing:

A series of nonclinical testing was performed to verify substantial equivalence of delefilcon A contact lenses to the predicate device. Non-clinical biocompatibility testing was conducted in accordance with the GLP regulation (21 CFR Part 58). The results of all non-clinical testing demonstrate:

- The lens material and extracts of the device are non toxic and non-irritating.
- The device has optical, dimensional and physico-chemical properties in common with currently marketed soft contact lenses intended for vision correction and consistent with or better than, the predicate lenses tested.
- The lenses are compatible with commonly available contact lens rewetting drops and saline solutions.

### Clinical Testing:

A three-month clinical study was conducted to assess the safety and efficacy of DAILIES TOTAL1® (delefilcon A) soft contact lenses for single use, daily disposable wear. The clinical study also provided data to establish substantial equivalence with the predicate, control lens.

The study evaluated 60 delefilcon A (test) subjects in a 2:1 ratio with the 30 naraafilcon B (control) subjects in a prospective, randomized, parallel group design. The primary safety and efficacy variables were biomicroscopy findings and visual acuity respectively. Additional variables tested include refraction, keratometry, and subjective ratings of vision, comfort and handling.

The study results showed similar performance between the test delefilcon A and control naraafilcon B lenses in the clinically relevant areas of fit, vision, comfort, health and handling when worn on a daily disposable wear basis.

### Risks and Benefits:

The risks of the subject device are the same as those normally attributed to the wearing of silicone hydrogel contact lenses on a single use, daily wear basis. The benefits to the patient are the same as those for other silicone hydrogel contact lenses.

### Substantial Equivalence:

Delefilcon A soft contact lenses are substantially equivalent to the predicate contact lens and similar to other daily wear soft contact lenses in terms of material water content (33% water), ionic characteristics, ISO Group V: silicone hydrogel and indications for use.

Any differences which may exist between the delefilcon A soft contact lens and other ISO Group V silicone hydrogel soft contact lenses do not adversely affect the safety and effectiveness of the device when worn under single use, daily wear conditions.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room --WO66-G609  
Silver Spring, MD 20993-0002

Ciba Vision Corporation  
c/o Ms. Alicia M. Plesnarski, RAC  
Director, Regulatory Affairs  
11460 Johns Creek Parkway  
Duluth, GA 30097

MAR 30 2012

Re: K113168

Trade/Device Name: DAILIES TOTAL1® (delefilcon A) Soft Contact Lenses  
for Daily Disposable Wear

Regulation Number: 21 CFR 886.5925

Regulation Name: Soft (hydrophilic) Contact Lens

Regulatory Class: Class II

Product Codes: LPL, MVN

Dated: March 21, 2012

Received: March 22, 2012

Dear Ms. Plesnarski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

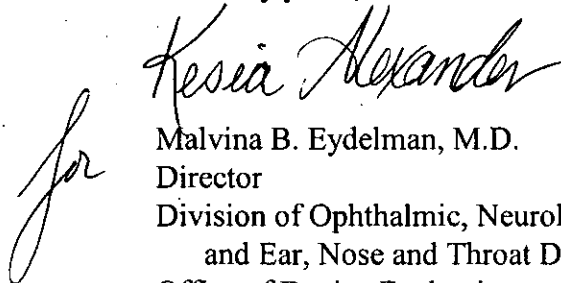
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in cursive script that reads "Kesia Alexander". To the left of the signature is a large, stylized handwritten "for" in cursive.

Malvina B. Eydelman, M.D.  
Director  
Division of Ophthalmic, Neurological,  
and Ear, Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K113168

**Indications for Use**

510(k) Number (if known): K113168

Device Name: DAILIES TOTAL1® (delefilcon A) Soft Contact Lenses

**Indications For Use:**

DAILIES TOTAL1® (delefilcon A) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism.

DAILIES TOTAL1® (delefilcon A) toric soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with 6.00 diopters (D) or less of astigmatism.

DAILIES TOTAL1® (delefilcon A) multifocal soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have up to approximately 1.50 diopters of astigmatism.

DAILIES TOTAL1® (delefilcon A) multifocal toric soft contact lenses are indicated for the optical correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in phakic or aphakic persons with non-diseased eyes. The lenses may be worn by persons who have 6.00 diopters (D) or less of astigmatism and who may require a reading addition of +3.00 diopters (D) or less.

The lenses are to be prescribed for single use, daily disposable wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

Prescription Use: X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Marc Robbott  
(Division Sign-Off)  
Division of Ophthalmic, Neurological and Ear,  
Nose and Throat Devices

510(k) Number K113168